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One Stamford Forum Stamford, CT 06901-3431 www.purduepharma.com

August 19, 2005

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800) Center for Food Safety and Applied Nutrition 5100 Paint Branch Parkway College Park, MD 20740



Dear Sir or Madam:

Purdue Products L.P. submits the information in this notification pursuant to 21 C.F.R. Subpart F, section 101.93 as notice of marketing structure/function claims for Senokot® brand Wheat Bran Fiber Supplement.

Supplement:

Senokot® brand Wheat Bran Fiber Supplement

Manufacturer/

**IFP Custom Processing Group** 

Packager:

2125 Airport Drive

Faribault, MN 55021

Distributor:

Purdue Products L.P. One Stamford Forum Stamford, CT 06901-3431

Statement Text:

- "Decreases (shortens) intestinal transit time"
- "Helps increase the frequency of bowel movements"
- "Helps promotes regularity by increasing bulk volume and water content of the stool"
- "Contains fiber, which provides bulk to the diet"
- "Softens the stool by holding water in the stool"
- "Softens the stool and may help reduce straining"

Name of dietary ingredient that is the subject of statement: Wheat Bran

Name of dietary supplement: Senokot® brand Wheat Bran Fiber Supplement

All of the above statements will be followed by an asterisk that links it to the following boxed warning, "This statement has not been evaluated by the Food and Drug Administration. The product is not intended to diagnose, treat, cure or prevent any disease."

I hereby certify that the information presented and contained in this notice to be accurate and in compliance with supplement label regulations, and that Purdue Products L.P. has substantiation to verify that the statements are truthful and not misleading.

David Grob, MS, RAC

Sr. Director, OTC Regulatory Affairs

Purdue Products L.P.

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